In the Supreme Court of the United States

OCTOBER TERM, 1973

No. 72-1686

DIANOVIN PHARMACEUTICALS, INC., A CORPORATION AND NICOLAS O. CABRERO ORONOZ, AN INDIVIDUAL, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF AA'PPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A 31-36) is reported at 475 F. 2d 100. The opinion and order of the district court (Pet. App. B 37-50) are reported at 342 F. Supp. 724.

JURISDICTION

The judgment of the court of appals was entered on March 16, 1973. The petition for a writ of certiorari was filed on June 13, 1973. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether the court of appeals correctly affirmed the district court's reinstatement of an injunction restrain-

ing petitioners from further violations of the adulteration and misbranding provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 332(a), 331(a), 351(a)(2)(B).

STATUTES INVOLVED

Section 302(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 332(a)) provides:

> The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of Title 28, to restrain violations of section 331 of this title, except paragraphs (h) - (j) of said section.

Section 301 (21 U.S.C. 331) provides in pertinent part:

> The following acts and the causing thereof are hereby prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
>
> * * * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) aftr shipment in interstate commerce and results in such article being adulterated or misbranded.

Section 501 (21 U.S.C. 351) provides in pertinent part:

A drug or device shall be deemed to be adulterated—

(a) * * * (2) * * * (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; * * *.

STATEMENT

The petitioners seek reversal of an order of the court of appeals affirming the district court's reinstatement of a permanent injunction restraining continued violations by petitioners of the adulteration and misbranding provisions of the Federal Food, Drug, and Cosmetic Act.

Investigations by the Food and Drug Administration from 1965 through 1969 showed that Dianovin Pharmaceuticals, Inc., a corporation organized and existing under the laws of the Commonwealth of Puerto Rico, and Nicolas O. Cabrero Oronoz, president of the corporation, were committing violations of the Act. In January 1969, an action to enjoin these violations was commenced in the district court pursuant to 21 U.S.C. 332(a). After an evidentiary proceeding, the district court entered Findings of Fact, Conclusions of Law, and an Order of Permanent Injunction

on February 17, 1969.[1] The court found, *inter alia*, that the petitioners pack, process, label and hold various drugs at their establishment in Santurce, Puerto Rico; that petitioners hold out for sale a number of drugs the components of which were shipped in interstate commerce; that petitioners' drugs are distributed in interstate commerce; that petitioners violated good manufacturing practices in manufacturing, processing, packing and holding the drugs[2]; and that several other violations of the adulteration and misbranding prohibitions of the Act had occurred.[3] The permanent injunction restrained petitioners from further violations of 21 U.S.C. 331(a) and (k); required operation of petitioners' plant in conformity with the good manufacturing practice regulations[4]; granted access to inspect the plant by FDA inspectors pursuant to 21 U.S.C. 374; and required generally that drugs processed by petitioners be brought into compliance with requirements of the Act. The district court retained jurisdiction for the purpose of enforcing or modifying the decree.

No appeal was taken from the order[5] and it re-

---

[1] The court's Findings of Fact and Conclusions of Law are unreported.

[2] 21 U.S.C. 351(a)(2)(B).

[3] 21 U.S.C. 351(b) (not in conformity with compendium standards), 21 U.S.C. 351(c) (strength and purity different than represented for non-compendium drugs), 352(a) (false and misleading labeling) 352(f)(1) (inadequate directions for use), and 353(b)(4) (failure to bear the statement "Caution: Federal law prohibits dispensing without prescription").

[4] 21 C.F.R. 133.1-133.15.

[5] A motion by petitioners to dissolve the injunction was denied in December 1969 (Pet. 9).

mained in effect until June 1970 when, pursuant to agreement of the parties, the district court entered an order suspending the terms and conditions of the permanent injunction. The order specifically provided that the injunction would revert to its full force and effect at such time as the government presented evidence that petitioners were violating the good manufacturing practice requirements of the Act, or that any drug manufactured by petitioners was found to be adulterated or misbranded within the meaning of the law.

In May 1972, after a hearing on a motion by the government to reinstate the injunction, the district court vacated the suspension order and reinstated the permanent injunction (Pet. App. B). On March 16, 1973, the court of appeals affirmed the order reinstating the injunction (Pet. App. A). The court of appeals held that "[t]he evidence of seriously deficient conditions and practices at appellants' plant, coupled with a history of unsuccessful efforts to obtain compliance by appellants with laws designed to protect the health and lives of the public, more than warranted injunctive relief" (Pet. App. A 35-36). In rejecting a jurisdictional challenge raised by petitioners in a motion for reconsideration in the district court, the court of appeals held that the government did not have to prove again at the reinstatement hearing that the drugs had been introduced into interstate commerce (Pet. App. A 33) and that the facts conceded by petitioners on appeal were sufficient, in any event, to establish jurisdiction (Pet. App. A 34-35).

ARGUMENT

1. The petitioners assert that the district court lacked jurisdiction because the drugs petitioners sold were not

distributed in interstate commerce. That assertion is directly contrary to the findings entered by the district court simultaneously with the unappealed final judgment in the original injunction proceeding. The court stated in Finding No. 3:

> The defendants operate a drug establishment at 1108 Las Palmas, Santurce, Puerto Rico, in which they manufacture, pack, process, label, and hold various articles, from which they distribute those articles in interstate commerce, and at which they held for sale a number of those articles after shipment of one or more of their components in interstate commerce.

The court of appeals doubted that petitioners could attack that finding in a post-judgment proceeding to reinstate the injunction. In any event, the court ruled that "if appellants, at this late date, had wished to raise a jurisdictional defense, the burden of proving the necessary facts was theirs" (Pet. App. A 34). The court's holding that petitioners did not meet that burden by means of their unsubstantiated motion for reconsideration is manifestly correct and does not warrant further review.

2. Moreover, the district court's jurisdiction also rests upon a finding that components of the drugs sold by petitioners were shipped in interstate commerce. Petitioners do not dispute the accuracy of that finding. They contend, instead, that the shipment of components does not satisfy the jurisdictional requirements of the Federal Food, Drug, and Cosmetic Act. The court of appeals correctly rejected that contention (Pet. App. A 34-36). We rely on that court's opinion, which answers each of petitioners' arguments on this point.

CONCLUSION

For the reasons stated, the petition for a writ of certiorari should be denied.

Respectfully submitted.

ROBERT H. BORK,
Solicitor General.
THOMAS E. KAUPER,
Assistant Attorney General.
CARL D. LAWSON,
HOWARD S. EPSTEIN,
Attorneys.

PETER BARTON HUTT,
Assistant General Counsel,
JEFFREY B. SPRINGER,
Attorney,
Food and Drug Division,
Department of Health,
Education, and Welfare.

AUGUST 1973.

DOJ-1973-08